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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	8

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/421,106	BYRUM, JOSEPH R.	
	Examiner	Art Unit	
	Young J. Kim	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) 11-15 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
18)☐ Interview Summary (PTO-413) Paper No(s). _____
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-10 and SEQ ID NO. 1-10 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that treating all claims as a single entity would expedite the prosecution and therefore, would not pose a serious burden. Furthermore, Applicants argue that examination of more than 10 sequences would not present an undue burden. This is not found persuasive because the structures of nucleic acids of I and proteins of II, and transformed plants of III, although might be related, comprise different structure and different functions, ultimately resulting in different searches being made. In regards to applicants traversal to the election of 10 SEQ ID Nos, each single SEQ ID Number is searched in all commercial, pending, and issued databases. Therefore, searching of 10 SEQ ID Number alone, comprise searching in multiple databases for each of the 10 SEQ ID Numbers. Furthermore, applicants are given **one** SEQ ID Number per application (as discussed in the written Restriction/Election Requirement), this practice is partially waived and Applicants are given up to **ten** SEQ ID Numbers per application. Furthermore, the 10 Sequence Restriction applies to all of the claims being examined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The specification is objected to by the Examiner because it makes reference to an URL on the internet. For example, line 23 of page 1 contains web-address (and page 2, 6, etc.). While information on web-address is accessible, the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

If the subject matter which is improperly incorporated by reference is directed to nonessential material (illustrating the state of the art), the deletion will probably not be considered as new matter. However, if the subject matter which is improperly incorporated by reference is directed to essential material, applicant will be required to amend the specification to include the subject matter incorporated. The amendment must be accompanied by an affidavit or declaration executed by the applicant stating that the amendatory material consists of the same material incorporated by reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7are indefinite for reciting SEQ ID Nos which are non-elected. Amending the claim to recite, "...nucleic acid sequence selected from the group consisting of SEQ ID NO: 1-10" overcome this rejection.

Claims 1-7 are indefinite for the recitation of the phrase, "said nucleic acid molecule capable of specifically hybridizing to a second nucleic acid molecule." It is unclear what is implied by the term "specifically."

Claims 8-10 are indefinite for being drawn to SEQ ID Nos which are non-elected. Amending the claim to recite the corresponding elected SEQ ID Numbers would overcome this rejection.

Claims 9-10 are indefinite for the recitation of the phrase, "nucleic acid molecules having one or two of said [pair of] defined ends" [phrase added from claim 8 for antecedent]. It is unclear how a nucleic acid molecule could have more than two defined ends (i.e., 5' end and 3' end).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS;

repeated from http://www.uspto.gov/web/menu/utility.pdf]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. § 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

[See also the MPEP at §§ 2107 - 2107.02].

The claimed nucleic acid is not supported by a specific asserted utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds may be useful as probes or markers for assisting in the isolation of full-length cDNAs or genes which would be used to

make protein and optionally further usage to isolate of homologous sequences, molecular weight markers, chromosomal markers, and for numerous other generic genetic engineering usages. These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed.

Further, the claimed nucleic acids are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a polymorphic nucleic acid may be utilized to obtain a polymorphic protein. The polymorphic protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. Identifying and studying the properties of a protein encoded by a nucleic acid, or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acids such that another non-asserted utility would be well established for the compounds.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 1-10 which corresponds to nucleic acid sequences. SEQ ID NO: 1-10 meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1-10 are directed to encompass gene sequences (that could include any microsatellite sequences, single polynucleotide polymorphism, etc), sequences that hybridize to SEQ ID NO: 1-10, or fragment thereof, which would include sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1-10, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008,

1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 1-10 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu et al. (WO 9910535 **1999**) (SEQ ID No 5), Imsande et al. (Sequence Homology Search **1999**) (SEQ ID No 7).

Claims are drawn to a substantially purified nucleic acid molecule capable of hybridizing to a nucleic acid sequence selected from the group consisting of SEQ ID No: 1-10, or complement, or fragment thereof.

Liu et al. disclose a nucleic acid sequence which has 80% local similarity match to the claimed SEQ ID No 5 (entire document and Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Imsande et al. disclose a nucleic acid sequence which has 75.9% local similarity match to the claimed SEQ ID No 7 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Therefore, the references anticipate the invention as claimed.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Larkins et al. (US Pat 5,824,523 **1989**) (SEQ ID No. 2), Lindsay (Sequence Homology Search **1997**) (SEQ ID No 3), Shoemaker et al. (Sequence Homology Search **1998**) (SEQ ID No 4), Waterson (Sequence Homology Search **1997**) (SEQ ID No 6), Laten et al. (Sequence Homology Search **1998**) (SEQ ID No 8), Elder et al. (US Pat 5,736,378 **1998**) (SEQ ID No 9), and Nakamura (Sequence Homology Search **1998**)(SEQ ID No 10).

Claims are drawn to a substantially purified nucleic acid molecule capable of hybridizing to a nucleic acid sequence selected from the group consisting of SEQ ID No: 1-10, or complement, or fragment thereof.

Larkins et al. disclose a nucleic acid sequence which has 63.6% local similarity match to the claimed SEQ ID No 2 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Linsay discloses a nucleic acid sequence which has 76.7% local similarity match to the claimed SEQ ID No 3 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Shoemaker et al. disclose a nucleic acid sequence which has 65.4% local similarity match to the claimed SEQ ID No 4 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Waterson discloses a nucleic acid sequence which has 63.6% local similarity match to the claimed SEQ ID No 6 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Laten et al. disclose a nucleic acid sequence which has 94.2% local similarity match to the claimed SEQ ID No 8 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Elder et al. disclose a nucleic acid sequence which has 60.2% local similarity match to the claimed SEQ ID No 9 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Nakamura discloses a nucleic acid sequence which has 65.1% local similarity match to the claimed SEQ ID No 10 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Therefore, the references anticipate the invention as claimed

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Moineau et al. (US Pat 4,886,878 **1998**) (SEQ ID No 1).

Moineau et al. discloses a nucleic acid sequence which has 66.7% local similarity match to the claimed SEQ ID No 1 (Sequence Homology Search), therefore capable of hybridizing to the fragment of the claimed SEQ ID Number.

Therefore, the reference anticipates the invention as claimed

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631by facsimile transmission. The faxing of such papers

must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-9348 before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

09/06/00

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER